

Notice of Allowability

Application No.

09/685,010

Examiner

Samuel W Liu

Applicant(s)

TURLEY ET AL.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/11/02, 9/3/03 and 3/23/04.
2. ☒ The allowed claim(s) is/are 39-52.
3. ☒ The drawings filed on 05 October 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 11/7/03 & 3/23/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 5-6-04
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Art Unit: 1653

DETAILED ACTION

This Office action is in response to applicants' amendments filed 11 December 2002, which cancels claim 37, adds claim 38 and amends claims 1-4, 7-8, 10 and 21, the applicant's amendment filed 3 September 2003, which cancels claims 1-36 and 38 and adds claims 39-40, and applicants' amendment filed 23 March 2004, which adds claims 41-52. The amendments indicated above have been entered. The pending claims 39-52 are therefore examined in this Office action.

Note that the references cited in the IDS filed 7 November 2003, and the IDS filed 23 March 2004 have been considered by Examiner. Also, note that Applicant's submission of RCE filed 23 March 2004 for the current application is considered improper because the prosecution of this application is not closed (see the interview summary mailed 19 April 2004).

EXAMINER'S AMENDMENT

An Examiner's Amendment to the record appears below. Should the change and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Mary Ann Dillahunt on May 6, 2004. Applicants agree to delete SEQ ID NOs: 2-5 from the instant claims 39 and 45, and agree the examiner proposed amendment to claims 39, 45 and 47 (see below).

Amendments to the claims:

The pending claims 39, 45 and 47 have been amended as follows. Please replace the previous claims with the claim shown below.

Claim 39 (*Twice amended*): Change "comprising at least one amino acid sequence BX7B (SEQ ID NO:28)" to "comprising at least one BX7B motif consisting of amino acid sequence of SEQ ID NO:28"; and after "selected from the group consisting of", delete "SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5,".

Art Unit: 1653

Claim 45 (*Amended*): After “selected from the group consisting of”, delete “SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, SEQ ID NO:5,”.

Claim 47 (*Amended*): Change “adapted” to “formulated”.

Amendments to the specification:

The abstract is amended as follows:

The present invention provides compositions and methods for treating a tissue disorder associated with a response-to-injury process or proliferating cells in a mammal. The tissue disorders include fibrosis, inflammation, degeneration and invasive disorders such as those occur in cancerous cells. The methods provided herein include administering to the mammal, an effective amount of a composition that alters the activity of transition molecules within a cell. Transition molecules are shown to be comprised of hyaladherins, hyaluronans and associated molecules that regulate the transitional phenotype.

The following is an **Examiner's Statement of Reasons for Allowance**:

The prior art of record does not teach or suggest the disclosed polypeptide of less than 60 amino acid residues comprising at least on BX7B motif consisting of SEQ ID NO:28 sequence as set forth in the instant claim 39. Applicants add the composition claims 45-48 which are drawn to the elected invention, and the process claims 49-52 which are drawn to a method of treating a condition or tissue disorder associate with a response-to-injury process, proliferative or inflammatory disorder comprising administering to a subject the claimed polypeptide. Thus, claims 39-48 are drawn to the allowable products. In consideration of the method claims 49-52, pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), are subject to being rejoined. The claims 39-52 are therefore allowable over the art of record (see also the “Interview Summary” mailed 18 March 2004).

Any comments considered necessary by applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Art Unit: 1653

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The Examiner can normally be reached daily except alternate Fridays from 8:30 A.M. to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached at (571) 272-0951. The official fax number for Technology Center 1600 is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

SWL

Samuel W. Liu, Ph.D.

Art Unit 1653, Examiner

May 7, 2004

Karen Cechane Carba PhD

Abstract

The present invention provides compositions and methods for treating a tissue disorder associated with a response-to-injury process or proliferating cells in a mammal. The tissue disorders include fibrosis, inflammation, degeneration and invasive disorders such as those occur in cancerous cells. The methods provided herein include administering to the mammal, an effective amount of a composition that alters the activity of transition molecules within a cell. Transition molecules are shown to be comprised of hyaladherins, hyaluronans and associated molecules that regulate the transitional phenotype.